▼ Rudolf Riester GmbH & Co. KG · POB 35 · DE-72417 Jungingen

UPS
Office of Device Evaluation 510(k)
Document Mail Center (HFZ-401)
Center of Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockvilee, Maryland 20850, USA

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SECTION 2: Summary and Certification

1. Summary of safety and effectiveness information (could be released to the public)

Substantial equivalence

Our blood pressure manometers Empire N are substiantial equivalent to our blood pressure manometer Empire. The models are the same regarding purpose and function.
Empire N and Empire just differ with regard to design and the material of the housing. In all other respects, the are the same, especially regarding purpose and function. The new Empire model is much more state-of-the-art.

Comparision checklist:

New model Empire N	**Old model Empire**
Intended use: To measure the blood pressure	Yes
Housing made of robust plastic	Housing made of metal
Bulb made of latex	Yes
Mercury lock device	Yes
Tube from 0 to 300 mmHg	Yes
Same cuffs available	Yes
Same purpose (blood pressure meter)	Yes
Same technical function	Yes
Maximum error throughout range +/- 3 mmHg	Yes
Robust plastic basket behind the manometer	Metal basket in front of the manometer
Available as desk, wall, stand and aneasthetic model	Yes
The new and the old model were both tested according to international standards and proved to be safe and effective. The instructions include all information regarding the safe handling with mercury and also what to do if mercury spills out.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

Rudolf Riester GmbH & Co. KG
c/o Ms. Patricia Riester-Freudenmann
President
P.O. Box 35
BruckstraBe 31
DE-72417 Jungingen
Germany

Re: K002955
Trade Name: Empire N Blood Pressure Manometers
Regulatory Class: II (two)
Product Code: DXQ
Dated: September 16, 2000
Received: September 22, 2000

Dear Ms. Riester-Freudenmann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further

announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K002955

Device Name: EMPIRE N Blood Pressure Manometer

Indications for use:

Empire N are blood pressure devices to measure the human blood pressure.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K002955